

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Howard Kaufman and Michal K. Bereta	Art Unit:	1632
Serial No.:	10/789,627	Examiner:	Anoop Kumar Singh
Filing Date:	February 26, 2004		
Title:	COMPOSITION FOR DELIVERING AN AGENT TO A TARGET CELL AND USES THEREOF		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

We, Howard Kaufman and Michal K. Bereta declare as follows:

1. We are applicants of the above-identified patent application (hereinafter "Application").
2. We are co-inventors of the subject matter of the pending claims, *i.e.*, claims 1-29, 33-61 and 65, which are directed to a composition for delivering an agent to a target cell comprising a microorganism that has on its cell surface an exogenous molecule that binds to an antigen on the surface of the target cell, and methods of treating neoplasia in a subject using the composition. We conceived of the invention claimed in this application.

3. We are co-authors of Bereta et al. (*Cancer Res.*, (2002) Vol. 43: Abstract No. 3288, p. 663) entitled "Construction of a recombinant salmonella vector displaying anti-CEA antibody: A novel method for targeting colon adenocarcinomas," along with Robert T. Glover, Andrew Hayhurst, Anna M. Wu, and Fumiko Arakawa.
4. We are informed and believe that this reference has been cited by the Examiner of the above-identified application at the U.S. Patent and Trademark Office. The work described in the Bereta et al. reference cited by the Examiner describes our own work.
5. Robert T. Glover, Andrew Hayhurst, Anna M. Wu, and Fumiko Arakawa are not named as co-inventors on the Application because they did not conceive of the claimed invention but were involved in the project after its conception in non-inventive capacities.
6. In 2002, an attenuated Salmonella strain VPN20009 was shown to be safe for human use in Phase I Clinical trials (Toso et al., (2002) *J Clin Oncol.* 20(1):142-52). We believe that a person of ordinary skill in the art would be able to extrapolate the effects of using the instant genetically engineered attenuated Salmonella strain in our tumorigenic mouse models to human subjects suffering from cancer.

7. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent in which this declaration is made.

11/13/07
Date

Howard Kaufman
Howard Kaufman, M.D.

Date

Michal K. Bereta, Ph.D.

Dkt. No.: 19240-461.US2
Application Serial No. 10/789,627
Page 3 of 3


7. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent in which this declaration is made.

Date

11.13.2007

Date

Howard Kaufman, M.D.



Michal K. Bereta, Ph.D.